



Selecting Cleanroom Storage Fixtures, Casework, and Cleaning Equipment: The Devil is in the Details

A GROWING NUMBER OF HOSPITALS AND OTHER PROVIDERS OF compounded sterile preparations (CSPs) are making sweeping policy changes to comply with the requirements of USP <797>, however, for many pharmacies, physical plant improvements are also required. Once the pharmacy decides the best course of action, maximizing their available resources is critical to the overall success of the project.

In some instances, the process of improving the physical plant is so arduous for pharmacy directors that simply getting administrative approval to proceed is monumental. Many strategies have been documented to navigate this maze of administrative rules and federal, state, and local regulations. The most important factor to the successful completion of the process in any pharmacy setting, be it in a 100-bed hospital or a 1,000-bed hospital, is to retain your central focus – the safety of the patients you serve.

This article will point out some of the ancillary supplies and devices that impact the daily functions and long-term success of any cleanroom. These seemingly peripheral items can actually substantively add to the quality of your final product and improve patient safety overall.

The Pitfalls

Once the necessary approvals have been granted, there can be a rush to get the project moving before a solid project plan is finalized. Perhaps more disturbing are situations in which the project plan created as part of the approval process is overlooked or cast aside. Pharmacy directors and project supervisors need to resist the temptation to simply identify the larger ticket items and pass the project along to another staff member to complete the balance of the purchases. Leaving the smaller details to other personnel or ancillary departments, who may not understand the overall project objectives, will yield a less than favorable result.

The “small details” are most often missed. However, these details not only maximize the functionality of the room, but also impact the quality of the CSPs. Some of these seemingly “small details” are:

- ▶ cleanroom carts
- ▶ storeroom carts
- ▶ prep room casework
- ▶ work carts
- ▶ work stations
- ▶ cleanroom seating
- ▶ supply carts
- ▶ work tables
- ▶ cleaning equipment
- ▶ transfer carts
- ▶ cleanroom storage

The Products

Cleanroom carts: In and around a cleanroom, all carts are not created equal. For the purposes of this discussion, carts will be separated into four distinct categories, delineated by their function:

- ▶ work carts
- ▶ transfer carts
- ▶ supply carts
- ▶ storeroom/warehouse carts



All photos courtesy of Certified Consultant Pharmacists, Inc.

Work carts are used to stage and organize drugs and supplies inside the cleanroom.

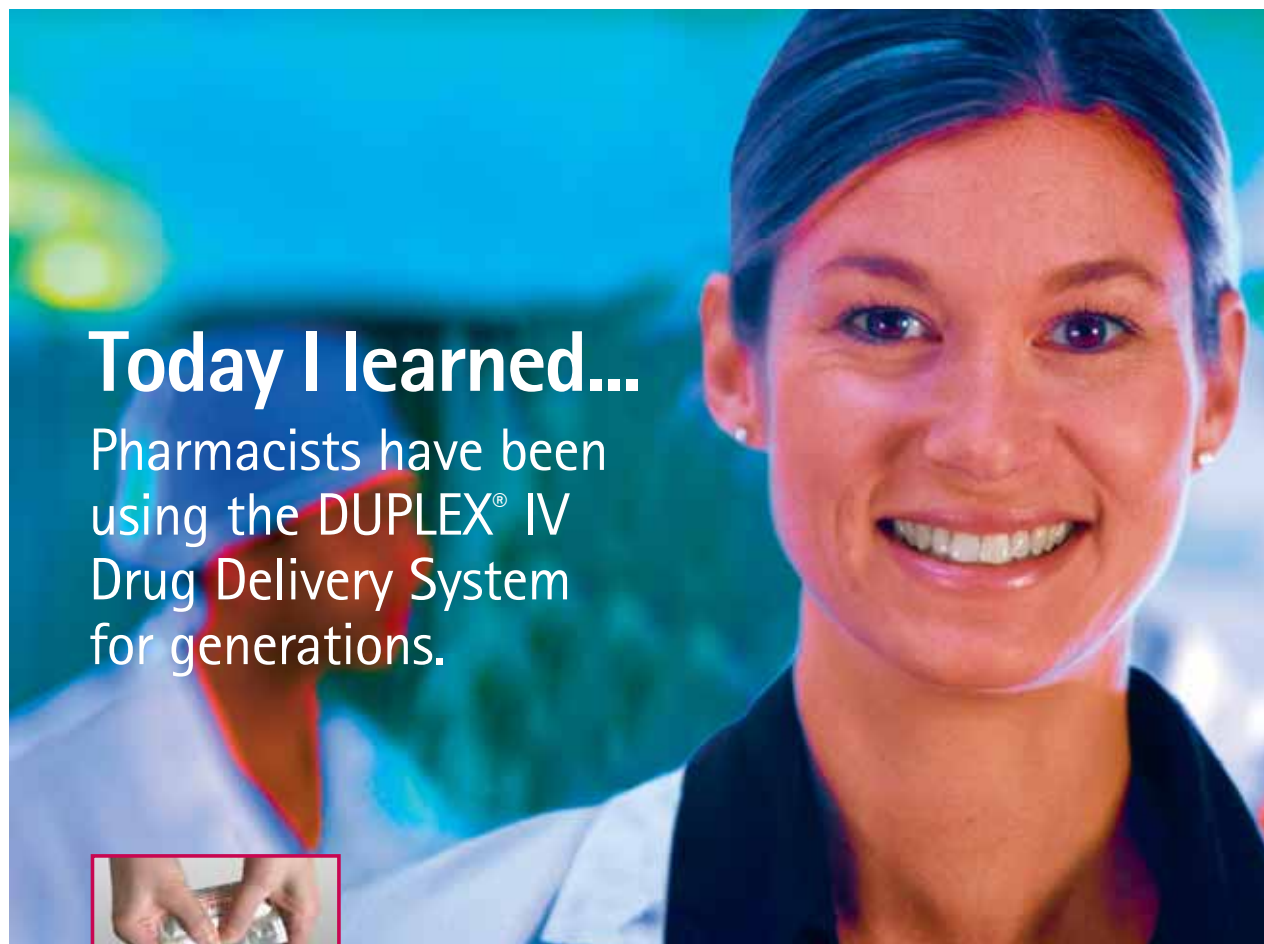
Work carts are usually small carts that a trained operator (pharmacist or technician) will use to stage and organize the drugs and supplies inside the cleanroom, before preparing the CSP at hand. This cart should be of sturdy stainless steel construction with solid shelving and wheels. The size of these carts may vary upon the size and scale of the cleanroom complex, but should allow a trained operator to bring it alongside any work area, not only as a convenience to the operator manning that area, but also to eliminate the operator’s tendency to introduce unnecessary objects or materials into the direct and contiguous compounding areas (DCCA). Most often these carts have dimensions of 18 by 24 inches or 18 by 30 inches with solid shelves and are 36 inches high, and are equipped with smooth wheels. In general, use of wired shelving carts in cleanroom applications make thorough daily cleaning difficult, and should be avoided.

Supply carts are used to organize and hold the minimal ancillary supplies needed to manipulate and compound the CSPs. As described in USP <797>, the cleaning and sanitizing of workspaces at the beginning of each shift require that all items be removed from the DCCA. So supply carts should not be stocked with more syringes, tubing, or other devices than necessary for that shift. These carts should be fitted with appropriate plastic bins that can also be cleaned and sanitized. Overstocking of these carts puts an undo burden on the cleanroom’s environmental controls, as well as the trained operators who must move and re-clean all of the overstocked items and bins before resuming compounding operations. These carts are usually larger than work carts, and although they are equipped with wheels, their movement dur-

ing the compounding day is limited. Supply carts are most often 24 by 60 inches or 36 by 60 inches with a maximum height of 60 inches, and are of perforated or louvered stainless steel construction. The use of perforated or louvered shelving allows for better airflow within the cleanroom than solid shelving, but at the same time these materials are easier to clean than the wire-shelf variety.

The term “supply carts” may also apply to carts that reside inside supply pass-throughs. In cleanroom complexes, in-dwelling carts may serve as mobile shelving to allow for the smooth transfer of drugs and supplies into and out of the compounding rooms, without requiring the trained operators to leave the compounding suite. Such transfer of materials also deters operators from having cleanroom doors open for too long, thereby decreasing the potential for contamination or excessive loss of air pressure. Supply carts’ dimensions are identical to their bin-carrying brethren, however, the overall height of the pass-through and its door clearances must be considered, especially from a height perspective. This will allow for the ease of movement and removal of these carts during the normal cleaning and sanitization cycles.

Transfer carts reside in the cleanroom complex, but never in cleanrooms themselves. These carts primarily move components to the pass-throughs or through the anteroom, so that operators can get the needed drug and supply components into the compounding areas. These carts can supplement the counter space and casework within the anteroom as well as “lighten the load” of the personnel staging drugs and supplies within the ante area. Items needing a wipe down before entering the cleanrooms may be spread out on these utilitarian carts. It should be noted that these carts should never leave the anteroom area or the confines of the pharmacy department. This practice will reduce the potential for cleanroom contamination from hallway, storeroom, or warehouse particles or debris. Transfer carts may be made of composite plastic that is washable and durable, and can stand up to the toughest sanitizing agents. These



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Cleanroom Equipment



Supply carts are used to organize the minimal ancillary supplies needed to manipulate and compound CSPs.

carts come in various sizes, styles, colors, and configurations to suit any size operation. All of your transfer carts should be equipped with smooth casters.

In an effort to reduce the bio-burden on the cleanroom complex, it is most advisable to have segregated **storeroom/warehouse carts** to move product from your warehouse, storeroom, or loading dock to the pharmacy. These carts are usually of large capacity and can handle the rigors of the job, or perhaps they are carts that have been reclaimed from other pharmacy duties. In either event, if they are of sufficient size and capacity, they will serve you well.

In anterooms – depending upon their individual configurations – it is sometimes optimal to forgo traditional casework for **work stations**, which enable you to customize their make-up to suit your organization's individual needs. Work stations also allow you to reconfigure your anteroom depending upon changes in workflow or the types of products being produced. These modular fixtures allow for varied counter heights, multiple shelf depths, and the flexibility to change their configuration based upon the changing needs of your department. They are available from several manufacturers and are produced in varying grades and materials, from solid stainless steel to food-grade stainless to zinc-coated chrome metals, as well as molded plastic cabinetry. Each varies in look, style, color, weight-bearing capacity, and cost. Almost without exception, a configuration can be found to fit your department's needs and budget.

In both the cleanrooms and anterooms, **mobile work tables** can provide flexibility and expanded capabilities, if used with fixed casework. They can allow for easy cleaning in and around your most critical work areas. Mobile work tables are most often of stainless steel design with solid tops and smooth wheels, measure 24 by 60 inches or 30 by 60 inches, and are counter-height. Although available with louvered or perforated tops, these fixtures should not be used in critical areas of the cleanroom when configured in that manner because of their immediate contact with HEPA-filtered airflow. Louvered or perforated tops can unpredictably redirect HEPA airflow within the critical (ISO Class 5) work areas and can cause unwanted turbulence within the cleanroom. Additionally, the perforations also make proper cleaning more difficult.

Cleanroom Storage

Storage in most pharmacies is at a premium. Cleanrooms within those pharmacies are no different. Careful consideration of the types of products and accounting for the general workflow inside the cleanroom are crucial to matching the

type and amount of storage to your needs. Storage systems are available from many reputable manufacturers. Consider the system's durability as it must withstand regular cleaning.

Nesting storage bins are a staple of the modern pharmacy department. As described above, supply carts need to have proper and well-fitting bins as part of their configuration. Since USP <797> requires that all items in the DCCA be cleaned and sanitized before each compounding shift, careful monitoring of the cleanroom stock is necessary, in order to limit the waste of time and products caused by the “overstuffing” of these storage systems. Many good suppliers provide interlocking and stacking storage bins. Bins that are pitted, cracked, or otherwise damaged should be removed from the cleanroom and replaced immediately.

Prep Room Casework

Prep room casework is central to the general construction of pharmacy work spaces; it can set the tone for the entire look and feel of the department. It can be as important to the quality of the drug preparations produced as the proper selection of the components of any prescription. That is to say, workflow design has been linked to reductions in error rates and retention of employees. The type and quality of the



Mobile work tables can provide flexibility in both cleanrooms and anterooms.

materials chosen for the pharmacy department's casework can account for a sizable portion of any department build or remodel. Many informative resources can be gathered in a simple Web search for pharmacy casework and storage solutions. There are many reputable firms that offer, as part of their service umbrella, design and layout assistance, space planning, and other assistance geared to maximize their company's particular products.

Casework, although central to the major work areas of the general pharmacy, has little role in the cleanroom itself. Careful attention to the materials and construction inside the anteroom can reap major benefits down the road. Laminate counters and wood products do not lend themselves too kindly to the type of cleaning and sanitizing agents used in and around the cleanroom complex. Further, because of the specific limitations and requirements for the cleaning of these areas as described in USP <797>, the mantra of “less is more” is most fitting. Fixed casework in your anteroom must be periodically emptied and cleaned. So washable surfaces and rounded edges are essential.

Cleanroom Seating

Cleanroom seating is always a point of discussion. Many manufacturers describe their products as “cleanroom chairs,” without considering the true meaning behind that statement. Permeable coverings, synthetic foams, oil-filled hydraulic pistons, and chrome-plated furnishings have no place in a controlled environment. As with



Cleanroom Equipment



In-dwelling carts may serve as mobile shelving to allow for the smooth transfer of drugs and supplies into and out of the compounding rooms.

any item brought into the DCCA, consideration must be given to the true need for seating. Proper seating should be provided in situations where an operator will be stationary for long periods of time. Cleanroom seating should be able to stand up to the rigors of the daily cleaning procedures you have established. The best cleanroom seating is of stainless steel and plastic construction, with smooth wheels and variable height adjustment.

Cleaning Equipment

Although USP <797> is clear regarding the frequency and general type of cleaning agents to be used, it allows for individual variance within that framework. Mops, handles, cleaning tools, and many specialized wipes, swabs, and other gadgets are available to make this facet of your cleanroom maintenance easier.

Involving several levels of staff – most importantly, the people who are actually responsible for the daily cleaning cycles – will be essential to developing a coherent and quality cleaning program that fits with your organization's overall quality mosaic. Trials of new mop handles, crevice tools, or wipes may sound trivial. However, since the labor component is one of the most expensive elements of your cleanroom, maximizing this resource is essential.

Care must be given to the selection of cleaning products, because products that look similar may have very different compositions. This is not only true of cleaners and sanitizing agents, but also of things as seemingly simple as cleanroom wipes. Be vigilant in your product selection process, and be sure to identify alternate items and suppliers, so that you do not end up damaging your pharmacy's most important piece of equipment – the cleanroom itself.

Final Thoughts

Many times, it is the sheer volume of information and number of choices available that can cause pharmacy directors and managers to delay critical decisions. Sometimes, obtaining assistance in identifying products that are consistent with both clinical best practices and local policies and procedures is all that is needed. USP <797>, in its essence, is in place to assure the quality of preparations we are providing, and the safety of the patients we are treating. ■



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WHERE TO FIND IT

Cleanroom Carts:

| Vendor | Reader Service Number | Website |
|-----------------------------------|-----------------------|--|
| InterMetro Industries Corporation | 80 | www.metro.com |
| Rubbermaid Medical Solutions | 29 | www.rubbermaidmedical.com |
| Terra Universal | 18 | www.terrauniversal.com |

Casework, Storage, and Workstations:

| Vendor | Reader Service Number | Website |
|-----------------------------------|-----------------------|--|
| InterMetro Industries Corporation | 16 | www.metro.com |
| Lionville Systems | 14 | www.lionville.com |
| MMI, Inc. | 10 | www.mmisystems.com |
| R.C. Smith Company | 9 | www.rcsmith.com |
| Terra Universal | 8 | www.terrauniversal.com |

Cleanroom Seating:

| Vendor | Reader Service Number | Website |
|---------------------------|-----------------------|--|
| Liberty Industries, Inc. | 7 | www.liberty-ind.com |
| Parkland Scientific, Inc. | 6 | www.parklandscientific.com |
| Terra Universal | 5 | www.terrauniversal.com |

Cleanroom Cleaning Products:

| Vendor | Reader Service Number | Website |
|----------------------------|-----------------------|--|
| Acute Care Pharmaceuticals | 50 | www.acutecareonline.com |
| ITW Texwipe | 51 | www.texwipe.com |
| Josco Products | 52 | www.joscoproducts.com |
| Liberty Industries, Inc. | 1 | www.liberty-ind.com |
| Micronova Manufacturing | 2 | www.micronova-mfg.com |
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| Williams Medical Company | 4 | www.williamsmedical.com |